IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

Palmetto Pharmaceuticals LLC, Plaintiff, v. AstraZeneca Pharmaceuticals LP, Defendant.	Case No. 2:11-cv-00807-SB-JDA **REPORT AND RECOMMENDATION OF MAGISTRATE JUDGE**

This matter is before the Court on Defendant's motion for summary judgment of no induced infringement. [Doc. 134.] Pursuant to the provisions of 28 U.S.C. § 636 and Local Civil Rule 73.02(C)(7), D.S.C., this magistrate judge is authorized to review pretrial motions and submit findings and recommendations to the District Court in cases referred for pretrial management.[1] For the reasons given below, the Court recommends Defendant's motion for summary judgment be denied.[2]

PROCEDURAL HISTORY

On April 5, 2011, Plaintiff filed its Complaint against Defendant, alleging infringement of U.S. Patent No. 6,465,516, entitled "Method of Stimulating Nitric Oxide Synthase." [Doc. 1.] On May 16, 2011, Plaintiff filed an Amended Complaint. [Doc. 27.] Defendant filed a motion to dismiss for failure to state a claim or, in the alternative, for summary judgment on June 15, 2011 [Doc. 41], which was granted as to Plaintiff's claims

[1]By Order of the Honorable Sol Blatt, Jr., filed November 15, 2011, this action was referred to the undersigned for pretrial management. [Doc. 51.]

[2]Also pending before the Court are Defendant's motions to strike Plaintiff's objectionable evidence [Doc. 201] and to exclude Plaintiff's experts Drs. Hallett, Elkayam, and Back [Doc. 203]. In an Order filed contemporaneously with this Report and Recommendation, the Court finds as moot Defendant's evidentiary motions.

of direct and contributory infringement and denied as to Plaintiff's claims of induced and willful infringement [Docs. 57, 80]. On February 15, 2012, Defendant filed an answer to the Amended Complaint, asserting numerous affirmative defenses and counterclaims. [Doc. 82.] Subsequently, Plaintiff filed a motion to dismiss Defendant's invalidity counterclaim and to strike Defendant's invalidity affirmative defense [Doc. 84], which was denied [Docs. 252, 260].

The parties agreed to pursue a path of limited discovery on the sole issues of infringement and inducement. [*See* Doc. 76.] On July 13, 2012, Defendant filed a motion for summary judgment of no induced infringement. [Docs. 134–48, 185–93.] On August 6, 2012, Plaintiff filed a response in opposition to Defendant's motion for summary judgment. [Docs. 195, 198.] Defendant filed a reply on August 21, 2012. [Doc. 200.] On November 29, 2012, the Court held a hearing on the three then-pending motions—for summary judgment, to strike, and to exclude. [Doc. 258.] Accordingly, the motion for summary judgment is ripe for review.

BACKGROUND

The '516 Patent

Plaintiff is the assignee and lawful owner of U.S. Patent No. 6,465,516, which issued on October 15, 2002, as amended by Reexamination Certificate No. 6,465,516 C1, which issued on April 5, 2011 (collectively "the '516 patent"). [Doc. 27 ¶ 6; Doc. 27-1; Doc. 27-2.] The '516 patent claims a method of treating nonhyperlipidemic subjects, i.e., people who

do not have hyperlipidemia,[3] who would benefit from increased nitric oxide ("NO") production. [Doc. 27 ¶ 7; Doc. 27-2 at 16, col. 1, ll. 27–29.] Claim 1 of the '516 patent, as amended during reexamination, claims the following:

> 1. A method for treating a nonhyperlipidemic subject who would benefit from increased Nitric Oxide production in a tissue comprising:
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> administering to the nonhyperlipidemic subject in need of such treatment a Hmg-CoA reductase inhibitor in an amount effective to increase Nitric Oxide production in said tissue of the subject.

[Doc. 27-2 at 16, col. 1, l. 27–col. 2, l. 5.]

CRESTOR® and Its Label/Package Insert

In 2003, Defendant began marketing a statin, rosuvastatin calcium, under the trademark CRESTOR®, which has become a widely prescribed statin. [Doc. 27 ¶ 13; Doc. 82 ¶ 13.] Also in 2003, the United States Food & Drug Administration ("the FDA") approved CRESTOR® for three uses, or indications, including the treatment of people with hyperlipidemia and, within that group, people with elevated cholesterol levels. [Doc. 27 ¶ 14; Doc. 82 ¶ 14.] Moreover, in 2003, Defendant began enrolling patients in a clinical trial, known as the JUPITER Trial, to evaluate the efficacy of CRESTOR® in reducing cardiovascular events for people who did not have hyperlipidemia but who did have cardiovascular risk factors. [Doc. 27 ¶¶ 15–16; Doc. 82 ¶¶ 15–16.] On February 8, 2010,

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[3] As Plaintiff explains in its Amended Complaint,

> Hyperlipidemia is a medical condition that usually includes having a high cholesterol level. Persons who are nonhyperlipidemic do not have high cholesterol levels. High cholesterol levels are considered to be abnormal.

[Doc. 27 ¶ 8; *see also* Doc. 263 at 7:2–10 (stating that patients who are non-hyperlipidemic do not have elevated levels of lipids or cholesterol or, generally, do not have elevated LDL).]

the FDA approved the use of CRESTOR® for indications resulting from the JUPITER Trial, including Indication 1.6, which is at issue in this case.[4] [Doc. 27 ¶ 25; Doc. 82 ¶ 25.] Following its approval, the FDA announced on its website: "This is the first time CRESTOR has been approved for use in the prevention of heart disease in individuals with 'normal' low-density lipoprotein (LDL) cholesterol levels and no clinically evident heart disease." [Doc. 27 ¶ 25; Doc. 82 ¶ 25.]

In the package insert accompanying CRESTOR®, Defendant instructs in Indication 1.6,

> In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥50 years old in men and ≥60 years old in women, [high sensitivity C-reactive protein ("hsCRP")] ≥2mg/L, and the presence of at least one additional cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, CRESTOR is indicated to:
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> - reduce the risk of stroke
> - reduce the risk of myocardial infarction
> - reduce the risk of arterial revascularization procedures

[Doc. 41-4 at 5.] Plaintiff alleges treating a nonhyperlipidemic individual having an elevated hsCRP by administering CRESTOR® ***is*** treating a subject who would benefit from

[4] On February 12, 2010—four days after the FDA approved the JUPITER indications— Plaintiff filed a request for ex parte reexamination of claim 1 of the '516 patent, citing a "substantial new question of patentability" relating to U.S. Patent No. 7,030,152 ("the Ridker patent"), which issued on April 18, 2006. [Doc. 27 ¶¶ 36–37; Doc. 82 ¶¶ 36–37; Doc. 141-8 at 3.] Plaintiff's stated reason for seeking reexamination was that the Ridker patent, which claimed a filing date eight days earlier than the '516 patent, was not cited in the original prosecution of the '516 patent, making the Ridker patent prior art. [Doc. 141-8 at 3.] Upon entering reexamination prosecution, Plaintiff removed the Ridker patent from consideration as prior art by submitting a declaration from the alleged inventor, swearing that his date of invention was before the Ridker patent's earliest priority date. [*Id.* at 20–24.] Plaintiff also amended claim 1. [*Id.* at 35–36; Doc. 195-78.] The '516 patent's reexamination certificate issued on April 5, 2011, the date this lawsuit was filed. [Doc. 27-2.]

increased NO production by administering an Hmg-CoA reductase inhibitor in an amount effective to increase NO production [Doc. 27 ¶ 46], and thus, Defendant infringes the '516 patent [*id.* ¶ 47].

THE PARTIES' POSITIONS

Motion for Summary Judgment

Defendant argues Plaintiff's inducement claim fails because Plaintiff cannot prove (1) specific instances of direct infringement or that CRESTOR® necessarily infringes the '516 patent and (2) Defendant had the requisite knowledge or specific intent to induce infringement. [Def.'s Mem. Supp. Summ. J. 22–34, Doc. 185.[5]] Specifically, Defendant contends no reasonable juror could find a relationship between CRP levels and NO production in humans such that measuring a patient's CRP level is the same as measuring a patient's NO production. [*Id.* at 28–31; *see also* Def.'s Reply to Pl.'s Resp. in Opp'n 8–13, Doc. 206 (replying to Plaintiff's opposition arguments).] Defendant also argues Plaintiff has no admissible evidence that Indication 1.6 or related promotional materials necessarily instruct or encourage infringement. [Def.'s Mem. Supp. Summ. J. 31, Doc. 185.] Further, Defendant contends the record evidence does not show that it has promoted CRESTOR® to increase NO levels in humans and that its activities in conducting research, performing necessary scientific functions, and following evolving scientific developments does not evidence induced infringement of the '516 patent. [*Id.* at 32–34;

[5]The parties have filed several documents under seal, such as their summary judgment briefs, which are accessible through CM/ECF by only court users and the filing party. However, all documents filed under seal were served on the opposing party. Therefore, the Court has cited sealed documents by their title and original pagination, for the benefit of the party that only received a hard copy of the document, and has included the CM/ECF Docket Entry Number for reference. For publicly accessible documents, the Court has cited only the CM/ECF Docket Entry Number and the corresponding pagination.

see also Def.'s Reply to Pl.'s Resp. in Opp'n 13–15, Doc. 206 (replying to Plaintiff's opposition arguments).]

Plaintiff contends there is substantial evidence that physicians and other health care professionals directly infringe the '516 patent because physicians prescribe CRESTOR® in accordance with Indication 1.6 and a person meeting the criteria of Indication 1.6 is necessarily a person in need of increased NO production. [Pl.'s Resp. in Opp'n 3–14, Doc. 198.] Specifically as to the relationship between Indication 1.6 and claim 1 of the '516 patent, Plaintiff argues (1) there is substantial scientific evidence linking elevated CRP levels to decreased NO production; (2) the position in this litigation of Dr. Verma, one of Defendant's experts, is at odds with his published writings; (3) the CRP/NO and statin/NO links are supported by a wide range of valid scientific studies, including human studies; (4) the PTO, whose findings are presumed correct and are entitled to deference, expressly found administering a statin to a subject with elevated CRP is administering a statin to a subject who would benefit from increased NO production; and (5) a person having other Indication 1.6 risk factors also is in need of increased NO production. [*Id.* at 5–14.] Plaintiff also contends there is substantial evidence that Defendant knowingly and intentionally induces infringement of the '516 patent. [*Id.* at 30–35.]

APPLICABLE LAW[6]

Summary Judgment

Rule 56 of the Federal Rules of Civil Procedure states, as to a party who has moved for summary judgment:

> The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.

Fed. R. Civ. P. 56(a). A fact is "material" if proof of its existence or non-existence would affect disposition of the case under applicable law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). An issue of material fact is "genuine" if the evidence offered is such that a reasonable jury might return a verdict for the non-movant. *Id.* at 257. When determining whether a genuine issue has been raised, the court must construe all inferences and ambiguities against the movant and in favor of the non-moving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

The party seeking summary judgment shoulders the initial burden of demonstrating to the court that there is no genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Once the movant has made this threshold demonstration, the non-moving party, to survive the motion for summary judgment, may not rest on the allegations averred in his pleadings. *Id.* at 324. Rather, the non-moving party must

[6] "The Federal Circuit applies its own law with respect to issues of substantive patent law and certain procedural issues pertaining to patent law, but applies the law of [its] sister circuits to non-patent issues." *Research Corp. Techs., Inc. v. Microsoft Corp.*, 536 F.3d 1247, 1255 (citing *In re Cambridge Biotech Corp.*, 186 F.3d 1356, 1368 (Fed. Cir. 1999). Summary judgment is such a procedural issue not affecting substantive patent law. *In re Cygnus Telecomms. Tech., LLC, Patent Litig.*, 536 F.3d 1343, 1351–52 (Fed. Cir. 2008). Therefore, in determining whether Defendant induced infringement, the Court will apply the law of the United States Court of Appeals for the Federal Circuit, and in determining whether Defendant is entitled to summary judgment, this Court will apply the law of the United States Court of Appeals for the Fourth Circuit.

demonstrate specific, material facts exist that give rise to a genuine issue. *Id.* Under this standard, the existence of a mere scintilla of evidence in support of the non-movant's position is insufficient to withstand the summary judgment motion. *Anderson,* 477 U.S. at 252. Likewise, conclusory allegations or denials, without more, are insufficient to preclude granting the summary judgment motion. *Ross v. Commc'ns Satellite Corp*., 759 F.2d 355, 365 (4th Cir.1985), *overruled on other grounds*, 490 U.S. 228 (1989). "Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson*, 477 U.S. at 248. Further, Rule 56 provides in pertinent part:

> A party asserting that a fact cannot be or is genuinely disputed must support the assertion by:
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> > (A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or
> >
> > (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.

Fed. R. Civ. P. 56(c)(1). Accordingly, when Rule 56(c) has shifted the burden of proof to the non-movant, he must produce existence of a factual dispute on every element essential to his action that he bears the burden of adducing at a trial on the merits.

Induced Infringement

Section 271(b) provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Even if a party is not liable for direct infringement, the party may be liable "for inducement [of] infringement of a method claim if it sells infringing devices to customers who use them in a way that directly infringes the method claim." *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1379 (Fed. Cir. 2005). To prevail, the patentee must establish three elements: "'[F]irst that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and [third] possessed specific intent to encourage another's infringement.'" *ACCO Brands, Inc. v. ABA Locks Mfr. Co., Ltd.*, 501 F.3d 1307, 1312 (Fed. Cir. 2007) (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304–05 (Fed. Cir. 2002)).

DISCUSSION

As stated, Defendant argues it is entitled to summary judgment because Plaintiff cannot prove (1) specific instances of direct infringement or that CRESTOR® necessarily infringes the '516 patent and (2) Defendant had the requisite knowledge or specific intent to induce infringement. However, Plaintiff has demonstrated a genuine issue of material fact remains as to each element of its inducement claim, and therefore, Defendant is not entitled to summary judgment of no induced infringement.

Direct Infringement

Defendant contends no reasonable juror could find a relationship between CRP levels and NO production in humans such that measuring a patient's CRP level is the same

as measuring a patient's NO production. [Def.'s Mem. Supp. Summ. J. 28–31, Doc. 185.] That is, Defendant argues Plaintiff has failed to demonstrate that anyone directly infringes claim 1 of the '516 patent by administering CRESTOR®.

As discussed, a patentee must establish direct infringement by some third party to prevail on a claim of induced infringement. *ACCO Brands*, 501 F.3d at 1312 (citation omitted). As set forth in the statute defining patent infringement, a party directly infringes a patent if the party, "without authorization[,] makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor." 35 U.S.C. § 271(a). A patent claiming a method, such as the '516 patent, "is directly infringed only by one practicing the patented method," *Joy Techs. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) (emphasis omitted), which requires actual performance of all of the steps of the patented method, either by the infringer or by one under the infringer's direction and control, *see, e.g.*, *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379–81 (Fed. Cir. 2007); *see also Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325,1334–35 (Fed. Cir. 2008) (holding the defendant was not liable for direct infringement of a method patent, even though it sold software containing instructions to perform the patented process, because the software did not actually perform the process); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008) (discussing the standard developed in *BMC Resources* for whether a method claim is directly infringed by the combined actions of multiple parties).

Here, Plaintiff has put forward sufficient evidence for a jury to conclude that a person meeting the criteria of Indication 1.6 is necessarily a "nonhyperlipidemic subject

who would benefit from increased NO production in a tissue" and that CRESTOR® increases NO production in humans; in other words, a genuine issue of material fact remains as to whether a doctor prescribing CRESTOR® pursuant to Indication 1.6 is necessarily infringing claim 1 of the '516 patent.[7] For example, Plaintiff has put forward evidence that shows

> (1) atherogenetic processes are initiated or accelerated in all conditions where an absolute or relative NO deficit is present [Doc. 195-56 (Tommaso Gori & Thomas Münzel, *Oxidative Stress and Endothelial Dysfunction: Therapeutic Implications*, 43 Annals of Medicine 259, 260 (2011))];
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> (2) CRP decreases NO [Nero Decl. Ex. E-1 (Esterline Ex. 17F) at AZP00469711, Doc. 198-1; Nero Decl. Ex. E-14 (Blasetto Dep. Ex. 7) at AZP00370739, Doc. 198-12[8]];

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[7]Before it can determine whether the defendant is infringing the patent at issue, a court must construe the claims at issue. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("Only when a claim is properly understood can a determination be made whether the claim 'reads on' an accused device or method, or whether the prior art anticipates and/or renders obvious the claimed invention."). Claim construction is a question of law and involves determining what the language of the claim means. *Markman*, 52 F.3d at 976, 979. Claim terms should usually be given their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1580 (Fed. Cir. 1996)). Here, at the November 29, 2012 hearing before the Court, the parties agreed the Court did not need to construe claim terms to resolve the motion for summary judgment. [Doc. 263 at 10:9–14, 67:16–18, 68:21–22.] Accordingly, for purposes of Defendant's summary judgment motion, the Court has considered the plain and ordinary meaning of the claim terms to be the meaning ascribed to the terms by Plaintiff, the non-moving party.

[8]As stated in the Order filed contemporaneously with this Report and Recommendation, the Court has considered Defendant's motion to strike Plaintiff's objectionable evidence [Doc. 201] as objections made pursuant to Federal Rule of Civil Procedure 56(c)(2). Defendant objects to the contents of the NO picture slides, arguing they are inadmissible hearsay. "'[T]he objection contemplated by [Rule 56(c)(2)] is not that the material "has not" been submitted in admissible form, but that it "cannot" be.'" *Ridgell v. Astrue*, No. DKC 10-3280, 2012 WL 707008, at *9 (D. Md. Mar. 2, 2012) (quoting *Foreword Magazine, Inc. v. OverDrive, Inc.*, No. 1:10-cv-1144, 2011 WL 5169384, at *2 (W.D. Mich. Oct. 31, 2011)). "[W]hen such an objection is made, the burden is on the proponent of the evidence to show that the material is admissible as presented or to explain the admissible form that is anticipated." *Gannon Int'l, Ltd. v. Blocker*, 684 F.3d 785, 793 (8th Cir. 2012) (citing Fed. R. Civ. P. 56 advisory committee's note). Thus, to overcome Defendant's objection, Plaintiff must show the allegedly objectionable evidence is admissible as presented or how the evidence may be admissible at trial.

Defendant contends the contents of the NO picture slides are inadmissible hearsay because

(3) rosuvastatin treatment improves basal NOS activity of the renal vasculature in hypercholestrolemic patients [Doc. 195-67 (Christian Ott et al., *Rosuvastatin Improves Basal Nitric Oxide Activity of the Renal Vasculature in Patients with Hypercholesterolemia*, 196 Atherosclerosis 704, 709 (2008))[9]]; and

(4) CRP levels are an independent determinant of basal NO activity improvement in humans after rosuvastatin treatment [Doc. 195-38 (C. Ott et al., *Rosuvastatin Improves Pulse Wave Reflection by Restoring Endothelial Function*, Microvascular Research (2012) at 1, 3:241–44)[10]].

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(1) Plaintiff has provided no foundational evidence for the articles on which the contents of the slides are based and (2) Plaintiff cannot rely on the learned treatise exception to the hearsay rule to admit the contents of the slides because no witness has sponsored the articles on which the contents of the slides are based. [Def.'s Mem. Supp. Mot. to Strike 13, Doc. 207.] Plaintiff argues the slides are not hearsay because (1) Plaintiff did not offer them for the truth of the matter asserted but, rather, as proof that Defendant believed, had knowledge of, and promoted a relationship between NO and CRP and (2) the slides are the statements of a party opponent or, at least, Defendant adopted the statements as its own. [Pl.'s Mem. in Opp'n to Def.'s Mot. to Strike 25–26, Doc. 225.] At this stage of litigation, for purposes of the motion for summary judgment, the Court is not convinced the contents of the slides are inadmissible hearsay because the slides were created by Defendant and, therefore, appear to be a statement of a party opponent. Thus, the Court overrules Defendant's objection to Plaintiff's use of the NO picture slides for purposes of summary judgment.

[9]Defendant objects to Plaintiff's use of the Ott 2008 paper, arguing the statement used from the Ott 2008 paper is inadmissible hearsay that Plaintiff failed to qualify for admission under the learned treatise exception because Plaintiff failed to proffer any testimony from any expert witness to sponsor the statement. [Def.'s Mem. Supp. Mot. to Strike 12, Doc. 207.] Plaintiff contends the article is admissible for purposes of summary judgment because Plaintiff may elect to use the article on cross-examination of an expert at trial and the article is a reliable authority, i.e., the article could be admissible at trial. [Pl.'s Mem. in Opp'n to Def.'s Mot. to Strike 19–22, Doc. 225.] The Court notes the article was published in a peer-reviewed journal, *Atherosclerosis*, from which Defendant's experts also cited articles, and therefore, the Court takes judicial notice that the journal is a reliable authority. The Court also agrees with Plaintiff that it could use the article to cross-examine experts at trial, and thus, the article may be admissible at trial. Accordingly, the Court overrules Defendant's objection to Plaintiff's use of the article for purposes of summary judgment.

[10]Defendant objects to Plaintiff's use of the Ott 2012 paper, arguing the statement used from the Ott 2012 paper is inadmissible hearsay that Plaintiff failed to qualify for admission under the learned treatise exception because Plaintiff failed to proffer any testimony from any expert witness to sponsor the statement. [Def.'s Mem. Supp. Mot. to Strike 8, Doc. 207.] Plaintiff contends the article is admissible for purposes of summary judgment because (1) it can be used at trial because it was relied upon by one of Plaintiff's experts, (2) it was published in a peer-reviewed journal by an organization that publishes many trusted scientific and medical information journals, and (3) Defendant has shown the article is a reliable publication by supporting the research and its authors. [Pl.'s Mem. in Opp'n to Def.'s Mot. to Strike 22, Doc. 225.] The Court takes judicial notice that the peer-reviewed journal *Microvascular Research* is a reliable authority, and Plaintiff could use the article at trial on cross-examination and, thus, the article may be admissible. Therefore, the Court overrules Defendant's objection to Plaintiff's use of the article for purposes of summary judgment.

From this representative evidence,[11] a reasonable jury could conclude that persons meeting Indication 1.6 criteria are in need of increased NO production and that treatment with CRESTOR® benefits such persons such that prescribing CRESTOR® pursuant to Indication 1.6 necessarily infringes claim 1 of the '516 patent. Therefore, a genuine issue of material fact remains as to the direct infringement element of Plaintiff's inducement claim.

Knowledge and Intent

Defendant contends the record evidence fails to show Defendant has the requisite knowledge and intent to be liable for induced infringement. [Def.'s Mem. Supp. Summ. J. 32–34, Doc. 185.] As stated, in addition to proving there has been direct infringement, to prevail on an inducement claim, the patentee must establish "that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *ACCO Brands*, 501 F.3d at 1312 (citation and internal quotation marks omitted). The knowledge requirement is "knowledge that the induced acts constitute patent infringement," which includes knowledge of the relevant patent. *Global-Tech Appliances, Inc. v. SEB S.A.*, --- U.S. ---, ---, 131 S. Ct. 2060, 2068 (2011); *see also DSU Med. Corp. v. JMS Co., Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc) ("[A]s was stated in *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990), '[t]he plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual

[11] The Court notes this is not an exhaustive list of the evidence put forward by Plaintiff that could establish a genuine issue of material fact as to whether a third party is directly infringing claim 1 of the '516 patent. However, at this procedural posture, because this representative evidence demonstrates a genuine issue of material fact exists as to whether a doctor prescribing CRESTOR® pursuant to Indication 1.6 is necessarily infringing claim 1 of the '516 patent, the Court need not address all evidence at this time.

infringements.' The requirement that the alleged infringer knew or should have known his actions would induce actual infringement necessarily includes the requirement that he or she knew of the patent." (second alteration in original)); *Mikkelsen Graphic Eng'g Inc. v. Zund Am., Inc.*, No. 07-C-0391, 2011 WL 6122377, at *7–8 (E.D. Wis. Dec. 8, 2011) ("Knowledge of a *risk* that the acts might constitute infringement is not enough; the inducer must *know* that the acts constitute infringement. . . . *DSU Medical* confirms that, in addition to knowing that a patent exists, an inducer must know that that patent will be construed in a way that results in the acts induced constituting infringement." (emphasis in original)).

To prove specific intent, the patentee must come forward with "[e]vidence of 'active steps . . . taken to encourage direct infringement,' such as advertising an infringing use or instructing how to engage in an infringing use, [which] show[s] an affirmative intent that the product be used to infringe." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005) (citing with approval patent law in copyright case) (quoting *Oak Indus., Inc. v. Zenith Elecs. Corp.*, 697 F. Supp. 988, 992 (N.D. Ill. 1988)); *see Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999) ("Inducement requires proof that the accused infringer knowingly aided and abetted another's direct infringement of the patent."). The requisite intent to induce infringement may be demonstrated through circumstantial evidence. *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988) (citation omitted); *see Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009) ("The question is not . . . whether a user following the instructions may end up using the device in an infringing way. Rather, it is whether [the] instructions teach an infringing use of the device such that we are willing to infer from those instructions an

affirmative intent to infringe the patent."); *see also Grokster*, 545 U.S. at 940 n.13 ("It is not only that encouraging a particular consumer to infringe a copyright can give rise to secondary liability for the infringement that results. Inducement liability goes beyond that, and the distribution of a product can itself give rise to liability where evidence shows that the distributor intended and encouraged the product to be used to infringe. In such a case, the culpable act is not merely the encouragement of infringement but also the distribution of the tool intended for infringing use."); *DSU Med.*, 471 F.3d at 1306 ("[I]nducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." (citing *Grokster*, 545 U.S. at 936–37; *Manville Sales*, 917 F.2d at 553)).

In this case, Plaintiff has demonstrated a genuine issue of material fact remains as to whether Defendant knew that its actions would induce infringement of the '516 patent and intended to induce infringement of the '516 patent. For example, Plaintiff has put forward evidence to show that Defendant knew of the '516 patent before Indication 1.6 was approved by the FDA[12] [Nero Decl. Ex. E-8 (Yates Dep. Tr.) at 61:8–62:6, 67:4–74:20, Doc. 198-8; Nero Decl. Ex. E-9 (Yates Dep. Exs. 5, 6), Doc. 198-9] and that Defendant knew that prescribing CRESTOR® pursuant to Indication 1.6 would necessarily infringe claim 1 of the '516 patent as described above [Nero Decl. Ex. E-8 (Yates Dep. Tr.) at 86:8–88:4,

[12]In its reply brief, Defendant contends the evidence fails to establish *Defendant* knew of the '516 patent because the email exchanges Plaintiff relies on to establish Defendant knew of the '516 patent at least as of November 2008 were between an employee of Plaintiff and an employees of AstraZeneca U.K. Limited, an entity different from Defendant AstraZeneca Pharmaceuticals LP. [Def.'s Reply to Pl.'s Resp. in Opp'n 18–19, 19 n.17, Doc. 206.] However, Defendant did not raise this issue at the hearing before the Court [*see* Doc. 263 at 30:3–11], and Plaintiff did not file a sur-reply. Therefore, without more, the Court concludes a genuine issue of material fact remains as to whether Defendant had the requisite knowledge to be liable for induced infringement.

Doc. 198-8; Nero Decl. Ex. E-11 (Yates Dep. Ex. 11), Doc. 198-10], yet Defendant subsequently promoted CRESTOR® for use pursuant to Indication 1.6 [Stover Decl. Ex. 11 (Lippman Dep. Tr.) at 40:14–41:1, Doc. 190]. From this representative evidence,[13] a reasonable jury could conclude Defendant knew inducing prescriptions pursuant to Indication 1.6 would infringe claim 1 of the '516 patent and Defendant specifically intended to induce such infringement. Therefore, a genuine issue of material fact remains as to the knowledge and intent elements of Plaintiff's inducement claim.

CONCLUSION AND RECOMMENDATION

Wherefore, based upon the foregoing, the Court recommends Defendant's motion for summary judgment [Doc. 134] be DENIED.

IT IS SO RECOMMENDED.

s/Jacquelyn D. Austin
United States Magistrate Judge

February 26, 2013
Greenville, South Carolina

[13] Again, the Court notes this is not an exhaustive list of the evidence put forward by Plaintiff that could establish a genuine issue of material fact as to whether Defendant had the requisite knowledge and intent to be liable for induced infringement.